REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. EXAMINER INTERVIEW

Applicants thank Examiner Kerr for the numerous telephone discussions wherein proposed claim amendments were discussed.

II. CLAIM STATUS & AMENDMENTS

Claims 1-31 were pending in this application when last examined.

Claims 1-22, 26 and 27 were examined on the merits and stand rejected.

Claims 23-25 and 28-31 were withdrawn as non-elected subject matter.

Claim 1 is amended to be in product-by-process format and to incorporate the limitations of claims 4, 16, 18 and 24 and the descriptions on page 12, lines 1-13, page 13, lines 1-13 and 20-23, page 14, lines 22-26 and line 34 to page 15, line 1.

Claims 1 and 17 have also been amended to clarify that the "microorganism" is transformed" (not the transformant is transformed) as supported by the disclosure at page 2, line 23 and original claim 6.

Claim 5 has been amended to depend on claim 1.

Claims 6 has been amended to include the designation "PF1022" and the full chemical name for PF1022, which is the substance produced by the microorganism as supported by the chemical formula in original claim 6 and the disclosure at page 11, lines 2-5.

Claim 7 has been amended to depend on claim 1 and to clarify that the substance PF1022 derivative is produced by the transformant of claim 1 as supported by the disclosure at page 10, line 13 to page 11, line 2 and original claims 7 and 25.

Claim 17 has been amended to depend on claim 1 and to further clarify the DNA added to the transformant. Support can be found in original claim 17.

Claim 19 has been amended to depend on claim 1 and to clarify that the microorganism of claim 1 is transformed. Support can be found in original claim 18.

Claims 20 and 21 has been amended to depend on claim 1.

Claim 23 has been amended to clarify the steps and culture conditions for the production of the peptide or depsipeptide as supported by the disclosure at page 17, line 1 to page 18, line 31 and original claim 23.

Claim 25 has been amended to clarify the steps and culture conditions for the production of the substance PF1022 derivative as supported by the disclosure at page 17, line 1 to page 18, line 31 and original claim 25.

Claims 26, 28 and 30 have been amended to recite "An isolated polynucleotide" as supported by the original claims and the disclosed Example starting at line 27 on page 20.

New claims 32-37 have been added.

Support for new dependent claims 32 and 36 can be found on page 11, lines 14-17.

Support for new independent claim 33 can be found in original claims 1, 16 and 19.

Support for new dependent claims 35 and 37 can be found in original claims 6 and 7.

Therefore, no new matter has been added by this amendment.

Claims 2-4, 8-16, 18, 22 and 24 have been canceled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any canceled subject matter.

Claims 1, 5-7, 17, 19-21, 23 and 25-37are now pending in this application.

The specification has been amended to correct the minor informalities noted by the Examiner and to delete reference to Norcardia parafinnica at page 14, line 5.

A revised Abstract is attached herewith which includes the genes

involved in the biosynthetic pathway from chorismic acid to p-aminophenylpyruvic acid as suggested by the Examiner. Support can be found at page 11, lines 18-21, at page 12, lines 5-35 and at page 14, line 22 to page 15.

. Support for the revised Abstract can be found in the original Abstract and at page

Therefore, no new matter has been added by this amendment.

III. OBJECTIONS TO THE SPECIFICATION AND ABSTRACT

In items 6-10 on pages 3-4, the specification and the abstract are objected for containing minor informalities.

It is respectfully submitted that the present amendment and the attached revised abstract overcome these objections. It is noted that the revised Abstract includes the genes involved in the biosynthetic pathway from chorismic acid to p-aminophenylpyruvic acid as suggested by the Examiner.

Specifically, the specification has been amended to correct the minor informalities noted by the Examiner and to delete reference to Norcardia parafinnica at page 14, line 5.

IV. CLAIMS OBJECTIONS

Claim 6 was objected to for containing a punctuation error. See item 9 on page 4. Claims 10-22 were also objected as improper multiple dependent claims. See item 10 on page 4.

It is respectfully submitted that the present amendment overcomes these objections for reasons which are self-evident.

V. INDEFINITENESS REJECTIONS

Claims 1-20 and 22 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for the reasons set forth in items 11-17 on pages 5-10 of the Office Action.

The present amendment overcomes these rejections for the following reasons.

In reply to items 11, 12, and 15, in amended claim 1, the three gene sequences involved in the "biosynthetic pathway" (i.e., the "biosynthesis genes") have been specified and the specific steps for transforming the microorganism to produce the transformant have been included as supported by the disclosure, for example, at page 12, lines 1-13, page 13, lines 1-13 and 20-23, page 14, lines 22-26 and line 34 to page 15, line 1. Further, the number of modifications is limited to "one to several" and a functional group containing a nitrogen atom is limited to a "nitro" or "amino" group. Also, the chemical name and formula of the secondary metabolite has been added for clarification.

In reply to items 13 and 15, claims 2-4, 8-16, 18, 22 and 24 were canceled. Thus, the rejections of items 13 and 15 should be withdrawn.

In reply to item 14, the term "one building block" has been changed with "one amino acid" for clarification. Also, attached herewith is copy of Maraheil et al., Chem. Rev., vol. 97, pp. 2651-2671 (1997) which describes the synthesis of antibiotics having peptide-bound backbones from building blocks.

In reply to item 16, claim 20 has been amended to recite "strain PF1022" as suggested by the Examiner.

Based on the above, the indefiniteness rejections of claims 1-20 and 22 under 35 U.S.C. § 112, second paragraph, are untenable and should be withdrawn.

VI. WRITTEN DESCRIPTION REJECTIONS

In item 17 on pages 8-10, claims 1-16, 18-20, 22 and 26 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks written description support for the broad genus of any gene involved in the biosynthetic pathway from chorismic acid to p-aminophenylpyruvic acid. In the 3rd paragraph on page 9, it is implicated that the disclosed species SEQ ID NO: 1-6 are not representative of the broader claimed genus.

In item 18 on pages 10-11, claims 6-18 and 22 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the claims are drawn to a transformant that can produce a particular metabolite that is claimed solely by function without any structural limitations on the transformant.

It is respectfully submitted that the present amendment overcomes these rejections.

During the interview, it was indicated that the above claim amendments should be sufficient to overcome the written description rejections.

Specifically, in reply to items 17 and 18, as discussed above, amended independent claim 1 is in product-by-process format and incorporates the limitations of claims 4, 16, 18 and 24 and the descriptions on page 10, line 9 to page 11, line 16, page 12, lines 1-13, page 13, lines 1-13 and 20-23, page 14, lines 22-26 and line 34 to page 15, line 1.

In other words, the claims have been amended to recite specific steps for transforming the microorganism to produce the transformant, including the specific sequences, i.e., SEQ ID NOS: 1-6, utilized in the process. Support for the use of SEQ ID NOS: 1-6 can be found in the disclosure, for example, at page 12, lines 1-13, page 13, lines 1-13 and 20-23, page 14, lines 22-26 and line 34 to page 15, line 1. In other words, the claims have been limited to SEQ ID NOS: 1-6, i.e., the specific structures identified by the Examiner has supported by the disclosure. See the 3rd paragraph of page 9 of the Office Action.

Based on the above, it is respectfully submitted that this product-by-process format is sufficient to adequately describe the transformant and imparts structural limitations on the transformant as described by the SEQ ID NOS and the specifically claimed chemical formulae for the resultant metabolites produced by the transformant.

In further reply to item 17, the number of modifications is limited to "one to several" and the type of modifications have been defined as a "substitution, a deletion, an insertion, and an addition." Support for the modifications can be found in the disclosure at page 13, lines 20-29, page 14, lines 28-33 and page 15, lines 3-8. Moreover, the functional activity of the enzyme has

been included as a positive limitation for the modified sequences as suggested by the Examiner during the interview.

Also, the claims have been amended to include the chemical designation, name and formula for the substances produced by the microorganism and transformant as described in the disclosure at page 10, line 9 to page 11, line 5.

In sum, the amended claims are drawn to the specific embodiments, i.e., SEQ ID NOS: 1-6 and the chemical formulae for PF1022 and the derivative thereof as exemplified in the disclosure. Accordingly, written description for the amended claims is satisfied by disclosure of: (1) a reduction to practice for each claimed embodiment (the making of the specifically deposited microorganism and transformant); (2) a reduction to drawings/chemical formulas (SEQ ID NOS: 1-6 & the chemical formulae); and (3) relevant identifying characteristics sufficient (such as structure or other physical and/or chemical properties) to describe the claimed invention in full, clear, concise and exact terms (SEQ ID NOS: 1-6 & the chemical formulae). Based on this disclosure, it is clear that the Applicant had possession of the amended claimed invention at the time of filing.

Based on the above, the written description rejections of claims 1-16, 18-20, 22 and 26 and claims 6-18 and 22 under 35 U.S.C. § 112, first paragraph, are untenable and should be withdrawn.

VII. ENABLEMENT REJECTIONS

In item 19 on pages 11-14, claims 1-22 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is enabling only for specific transformants of Mycelia sterilia containing genes encoding SEQ ID NOS: 2, 4, and 6 and the specifically disclosed metabolite, and not for any transformant using any gene nor for any metabolite.

It is respectfully submitted that the present amendment overcomes this rejection. Specifically, the claims have been amended to the specific transformants of Mycelia sterilia

containing genes encoding SEQ ID NOS: 2, 4, and 6 and the specifically disclosed metabolite, PF1022 and derivative thereof, as defined by their chemical name and formulae. In other words, the amended claims are limited to that which the Examiner indicated is enabled. Thus, the enablement rejection of claims 1-22 under 35 U.S.C. § 112, first paragraph in item 19, is untenable and should be withdrawn.

In item 20, on page 14, claims 20 and 21 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the deposited transformants fail to comply with the deposit rules for lacking a statement regarding the public availability of the deposited microorganisms.

It is noted that strain PF1022 and strain 55-65 were deposited under the terms of the Budapest Treaty with the National Institute of Bioscience and Human-Technology and assigned accession nos. FERM BP-2671 and FERM BP-7255, respectively, as evidenced by the deposit receipts submitted with the filing of the application. Furthermore, all restrictions on the availability of the deposits to the public imposed by the depositor will be irrevocably removed upon the granting of the U.S. Patent on the above-identified application. During the interview, the Examiner noted that such a statement made in the body of the response would be sufficient to overcome the rejection. Thus, the enablement rejection of claims 20 and 21 in item 20 is untenable and should be withdrawn.

VIII. NON-STATUTORY SUBJECT MATTER

In item 21 on pages 14-15, claims 26-27 were rejected under 35 U.S.C. § 101 on the basis that they are directed to non-statutory subject matter by reading on a product of nature.

The present amendment overcomes this rejection for reasons that are self-evident.

IX. ANTICIPATION REJECTIONS

Claims 1-5, 18 and 26 were rejected under 35 U.S.C. § 102(b) as anticipated by Blanc et al., Microbiology, vol. 23, no. 2, pp. 191-202 (1997). See items 22-23 on pages 15-16.

It is respectfully submitted that the present amendment overcomes this rejection for the following reasons.

As noted above, independent claim 1 was amended to incorporate the subject matter of claims 4, 10, 12, 14, 16, 18 and 24. Since claims 10, 12, 14, 16 and 24 were not included in this rejection, it is respectfully submitted that anticipation rejection is untenable as applied to the amended claims and should be withdrawn.

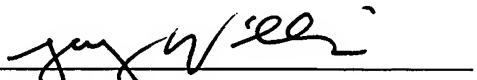
CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Koji YANAI et al.

By: 

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ATTACHMENTS

1. M.A. Marahiel et al., "Modular Peptide Synthetase Involved in Nonribosomal Peptide Synthesis", Chem. Rev., Vol. 97, pp. 2651-2673, (1997);

2. Revised Abstract